Appl. No.: 10/007,257
Amdt. dated 01/18/2005
Reply to Office action of November 18, 2004

REMARKS/ARGUMENTS

This Amendment is responsive to the Final Office Action dated November 18, 2004 and subsequent telephone interview of December 29, 2004 between the Examiner and J. Scott Young on behalf of the Applicants. Claims 1 – 4, 6 – 9, 11- 28 and 30 – 41 are pending in the application. Those Claims stand rejected. By way of this amendment, the Applicant has amended Claims 1, 2, 6, 24, and 25.

The Claims currently stand rejected in view of the Randen, Capone, and Novo references, and further in view of the combination of the Hawkins and Langley references. Amendments and remarks are presented herein to address the grounds of rejection and also to comply with several recommendations made by the Examiner during a telephone interview of December 29, 2004.

Each reference is addressed, in order, below. For ease of explanation, the inventors have prepared a summary of the characteristics of the invented particle and the reference particles with illustrations that demonstrate the distinctions between the claims and the references. The summary is attached hereto as Exhibit I and is referenced throughout the remarks.

Rejections in view of the Randen Reference

Claims 6 - 8, 10 – 12, 22, 24, 25, and 32 are rejected under 35 U.S.C. §102 and claims 1 – 12, 20 – 25, 27, and 32 – 41 are rejected under 35 U.S.C. §103 in view of the Randen reference.

Randen teaches coprecipitation of enzymes with a water-soluble starch by preparing an aqueous solution of enzymes and starch, and mixing the solution with organic solvent to cause precipitation. Applicants previously argued that the claimed composition excludes starch as a possible coprecipitant and is therefore distinguished from Randen. According to the Final Office Action and the telephone interview, the Examiner views the Markush groups of Claims 1 and 6 to be open ended to other constituents, such as starch, and additionally to include the possibility of starch as the polysaccharide recited in Claim 1 or the carbohydrate listed in Claim 6.

The Markush terminology of Claims 1, 6, 24, and 25 has been amended to use "consisting of" language, thereby closing the group of coprecipitant core materials to those

specifically recited within the respective claims. Also, Claims 1, 24, and 25 have been amended to delete recitation of polysaccharides and Claim 6 has been amended to delete recitation of carbohydrates as possible coprecipitant materials. The amendments are incorporated by dependency into Claims 2 – 5, 7 – 21, 33 – 35, 40, and 41. Therefore, Claims 1 – 21, 24, 25, 33 – 35, 40, and 41 are novel in view of the Randen reference. Remaining Claims 22 and 32 are novel over the Randen reference for reasons previously made of record. Specifically, Claim 22 recites a particle size not disclosed in Randen while Claim 32 recites an admixing step not disclosed in Randen.

Also, Claim 2 has been amended to more clearly reflect the crystalline nature of the recited coprecipitant core. As amended, Claim 2 demonstrates that the biological material is not incorporated within the core of the claimed water soluble particle.

In addition to distinguishing Randen on the basis of the starch coprecipitant material, Randen has not been shown to disclose, teach, or suggest a particle or manner of making a particle with the recited coprecipitant core. In contrast, Randen discloses that the enzyme is physically entrapped within the coprecipitant support matrix (p. 765, col. 2). So, if anything, Randen teaches away from the formation of a coprecipitant core. Referring to Exhibit I, specifically with reference to particles A and C, it is shown that the difference in core structure causes several distinsugihing characteristics between the compared particles. Namely, particles such as those of Randen (C) are typically much larger than the particles as claimed (A). In Randen-type particles, the majority of protein is blended within the interior of the particle and not accessible in the dried state. This makes the Randen-type particles unsuitable for applications such as imaging of biomolecules by probe microscopy or molecular imprinting. Further, on reconstitution back into aqueous, Randen-type particles release the protein into solution more slowly that particles of as claimed. Thus, the claimed particle has physical and performance distinctions that are not taught or suggested by the Randen reference.

Rejections in view of the Capone Reference

Claims 1 – 5, 24 – 28, 30, and 40 are rejected under 35 U.S.C. §102 and claims 1 – 12, 20 – 28, and 30 – 41 are rejected under 35 U.S.C. §103 in view of the Capone reference.

Capone relates to proteins adsorbed on the surface of zymosan particles or polymeric beads. As previously argued, a fundamental feature that makes the particles formed in Capone different from the particles according to the claimed invention, is that the particles in Capone are not water-soluble (see p. 2, lines 24 to 27; Ex. 1, lines 113-114; Ex. 2, lines 5 6). The solubility distinction and resultant criticality is demonstrated in Exhibit I, specifically with reference to particle type D. As shown, the distinct mechanism of producing the particle as disclosed in Capone results in differences in biocompatibility compare to the recited particle.

Since the recited particles are water-soluble and because the recited method produces water-soluble particles, the insoluble particles of Capone do not anticipate or suggest the claimed composition or method.

Rejections under 35 U.S.C. §103 in view of Novo '919

Method Claims 22 and 32 are rejected under 35 U.S.C. §103 in view of the Novo '919 reference. However, Claims 22 and 32 recite that coprecipitation occurs immediately after mixing of the macromolecule/coprecipitant solution with an organic solvent. and that the admixing step uses an excess of water miscible organic solvent or solvents. In contrast, Novo notes that special precautions need to be taken to avoid contaminating the solid crystalline lipase with solid-phase impurities. To avoid this it is suggested that the solvent be added in portions so that separation and subsequent removal of solid-phase impurities by filtration can take place. The skilled person reading the disclosure of Novo, would conclude that addition of excess solvent to a solution containing salt and protein would lead to phase separation of two phases.

Thus, the recited methods are distinguished from the disclosure of Novo, and there is no teaching or suggestion in Novo of a method that would result in a particle having a macromolecule coated upon a coprecipitant core.

Rejections under 35 U.S.C. §103 in view of Hawkins combined with Langley

Claims 1 – 5, 13 – 21, 23, 26 – 28, and 30 – 34 are rejected under 35 U.S.C. §103 in view of the Hawkins reference in combination with the Langley reference.

Both references generally teach a method of precipitating enzymes from aqueous solutions. However, the methods are fundamentally different, so one of ordinary skill in the art would not be motivated to combine the teachings of the references. Each of the methods begins with an aqueous solution or dispersion of polymer and enzyme. Hawkins combines the aqueous solution/dispersion with an organic solvent that is partly or fully miscible with the water of the aqueous solution to cause coprecipitation of the polymer and enzyme (col. 3, l. 28-30). Langley, on the other hand, combines the aqueous solution/dispersion (col. 4, l. 42-44) with an immiscible liquid and then azeotropes, i.e. distills, (Abstract) the combination to obtain a product of dry particles in water immiscible liquid (col. 6, l. 61-65). One of ordinary skill in the art would not be motivated to substitute the Hawkins method of coprecipitation using a miscible organic solvent with the Langley method of distilling using an immiscible azeotropic liquid. Therefore, the references have not properly been combined.

The Hawkins and Langley references would not teach or suggest the claimed invention even if combined. Each of the claims recites, directly or indirectly, a coprecipitate core having dehydrated biological macromolecule coated thereon. The composition of the coprecipitant core has been more clearly specified by the amendments to Claims 1 and 6. Particularly, Langley results in an enzyme distributed throughout a polymer matrix and therefore does not relate to a coating on a co-precipitant core. For example, in Langley on column 8, lines 35 – 36 it is specifically stated that "matrix particles having enzymes distributed throughout". Hawkins relates to preparing a stabilized enzyme dispersion wherein particles are initially produced with protein in a hydrated state. A separate drying process is required in Hawkins such as shown in Example 5. In complete contrast, the present invention relates to the biological macromolecule being in a dehydrated state. Thus, the teachings of the references, even if combined, fail to teach or suggest the invention as claimed, even if the particle size of Langley is combined with the teachings of Hawkins as proposed by the Examiner.

Conclusion

Applicants appreciate the Examiner's consideration and admission of the amended claims which do not raise new issues, but which, instead, incorporates claim amendments requested by the Examiner into the claims. In view of the amended claims and the remarks submitted above,

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it is respectfully submitted that the present claims are in condition for immediate allowance. It is therefore respectfully requested that a Notice of Allowance be issued. The Examiner is encouraged to contact Applicants' undersigned attorney to resolve any remaining issues in order to expedite examination of the present application.

It is not believed that extensions of time or fees for net addition of claims are required, beyond those that may otherwise be provided for in documents accompanying this paper. However, in the event that additional extensions of time are necessary to allow consideration of this paper, such extensions are hereby petitioned under 37 CFR § 1.136(a), and any fee required therefore (including fees for net addition of claims) is hereby authorized to be charged to Deposit Account No. 16-0605.

Respectfully submitted,

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I hereby certify that this paper is being facsimile transmitted to the U.S. Patent and Trademark Office Fax No. (703) 872-9306 on the date shown below.

Pamara Stevens — 1-18-2005 Date

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